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10/553,838	10/23/2006	Kiyoyuki Nakata	2005_1661A	6312

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EXAMINER	
WINSTON III, EDWARD B	
ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/553,838	NAKATA ET AL.	
	Examiner	Art Unit	
	EDWARD WINSTON	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/04/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The following Office action in response to communications received June 04,2010. Claims 1-15 have been amended. Therefore, claims 1-15 are pending and addressed below.

2. Applicant's amendments to the claims are sufficient to overcome the ***35 USC § 112 second paragraph,*** rejections set forth in the previous office action dated April 16, 2009.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-15 are not tied to a particular machine or apparatus nor do they transform a particular article into a different state or thing, thereby failing the machine-or-transformation test; therefore, claim 1-15 are non-statutory under § 101.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular it is not clear "makes reference to the storage member according to obtained order and combination of the medicine information". Examiner interprets limitation as a computer that has a communication interface for interconnecting to compounders.

Appropriate clarification and correction is required.

2. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular it is not clear what a "member" is. Examiner interprets the term can member CPU and the like or program. As defined in Microsoft Press Computer Dictionary; 3rd Addition, member is defined as - (n) In object-oriented programming, a variable or routine that is part of a class (i.e. C++ class). Appropriate clarification and correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "member" is used in Claims 1-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-8 and 11-14 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Yuyama et al. (US 7,333,938) in view of Kircher et al. (US 6,975,924)

CLAIM 1.

Yuyama et al. teach(s) a medicine management system, comprising:

- a storage member for storing medicine information on medicines (see at least Figure 1; Col 1 || 49-56) and combination modification information showing change when a plurality of medicines are combined (see at least Col 9 || 43-63); and
- a combination adequacy judging member for judging combination adequacy based on the combination modification information stored in the storage member when two or more medicines are included in information of one or more prescriptions for a certain patient, wherein (see at least Col 2 || 21-34)
- the storage member stores medicine codes associated with respective medicines and combination modification information corresponding to a combination of medicine information which include three or more medicines and is rearranged according to the medicine codes (see at least Col 2 || 45-63), and information about presence or absence of occurring combination modification based on the difference of combination order with reference to medicine information (see at least Figure 6; Col 2 || 3-10), and
- the combination adequacy judging member rearranges the medicine information according to the medicine codes stored in the storage member when two or more medicines are included in the prescription information (see at least Col 7 || 66-67, Col 8 || 1-16) ,

Yuyama et al. does not explicitly teach a system that searches whether or not the order and combination of the rearranged medicine information exist in the combination modification information invoked from the storage member, and judges combination adequacy. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the system of Yuyama et al. to include the apparatus preferably comprises a computer that contains a memory for storing instructions for operating the apparatus and for controlling compounders that prepare a prescription admixture, with the memory including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of the compounders that the apparatus is adapted to control. The apparatus determines the order of admixing by general rules of admixing and by categorized compatibility groups of components, so that the number of rinses that must be done are minimized (see at least Abstract) as taught by Kircher et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the system of Yuyama et al. in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known systems/methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

CLAIM 3.

Yuyama et al. further teach(s) a medicine management system as defined in claim 1:

- wherein the storage member stores a master file in which unrewritable combination modification information is stored and a case card file in which combination modification information can be newly stored, and during judgment of combination adequacy, the combination adequacy judging member judges combination adequacy preferentially based on the combination modification information stored in the case card file in priority to the master file (see at least Col 3 || 61-64).

CLAIM 4.

Yuyama et al. further teach(s) a medicine management system as defined in claim 1, further comprising:

- display member for displaying the combination adequacy judged in the combination adequacy judging member, wherein combination modification information on combinations of all medicines displayed in the display member can be displayed (see at least Figure 1, Col 6 || 4-6).

CLAIM 5.

Yuyama et al. further teach(s) a medicine management system as defined in claim 4:

- wherein the combination modification information on combinations of all medicines displayed in the display member can be changed and can be newly stored in the case card

file (see at least Col 9 || 43-63).

CLAIM 6.

Yuyama et al. further teach(s) a medicine management system as defined in claim 4:

- wherein after a medicine registration screen allowing a plurality of combined medicines to be registered with respect to each combination unit is displayed on the display member, all combinations among all combination units can be displayed by a list on a combined medicine confirmation screen, and new combination modification information can be inputted and stored in the case card file (see at least Figure 1-3, Col 3 ||65-67 and Col 4 || 1-3).

CLAIM 7.

Yuyama et al. further teach(s) a medicine management system as defined in claim 4:

- wherein the storage member stores the combination order according to combination of the medicine information including the case that the combination modification occurs based on the difference of the combination order, and (see at least Abstract)
- the combination adequacy judging member causes the display member to display the medicine information rearranged in the appropriate combination order when the medicine information which occurs the combination modification based on the difference of the

combination order is stored in the storage member when the storage member is searched based on the combination of the three or more kinds of rearranged medicine (see at least Abstract).

CLAIM 8.

The medicine management system as defined in claim 1:

- wherein when the prescription information includes two or more (each injection of the injection prescription; i.e. more then one) medicines (see at least Abstract),

Yuyama et al. does not explicitly teach a system that wherein the combination adequacy judging member selects medicines to be simultaneously administered based on procedure codes stored in the storage member before rearranging the medicine information according to the medicine codes. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the system of Yuyama et al. to include the controller computer 10 that may utilize the known compatibilities of components to enable concurrent compounding of such compatible components into the final bag or an intermediate mixing chamber. In addition, rinsing may be accomplished with a source solution which is compatible with both the solutions flowing through the rinsed portion before and after the rinsing. Thus, large volume additives may be transferred to the final container or bag or transferred to an intermediate mixing chamber at the same time as small volume additives or used as rinsing fluids. Such compatibility screening and concurrent compounding enables the present invention to maximize the speed in which admixtures are

compounded which results in more efficient use of the compounders, as well as the controller computer (see at least Col 10 || 66-67 and Col 11 || 1-13) as taught by Kircher et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the method of Yuyama et al. in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known systems/methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

CLAIM 11.

Claim 11 is directed to a system for a member for displaying the combination adequacy judged in the combination adequacy judging member, wherein combination modification information on combinations of all medicines displayed in the display member can be displayed. Claim 11 recites the same or similar limitations as those addressed above for claims 4. Claim 11 is therefore rejected for the same reasons as set forth above for Claim 4 respectively.

CLAIM 12.

Claim 12 is directed to a , wherein after a medicine registration screen allowing a plurality of combined medicines to be registered with respect to each combination unit is displayed on the display member, all combinations among all combination units can be displayed by a list on a combined medicine confirmation screen, and new combination modification information can be

inputted and stored in the case card file. Claim 12 recites the same or similar limitations as those addressed above for claims 6. Claim 12 is therefore rejected for the same reasons as set forth above for Claim 6 respectively.

CLAIM 13.

Yuyama et al. does not explicitly teach a system wherein when a stored combination of medicine information has combination modification due to difference in combination order, the storage member stores the change, and when the pertinent combination is referred, medicine information is rearranged in an appropriate combination order and displayed on the display member. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the system of Yuyama et al. to include the apparatus preferably comprises a computer that contains a memory for storing instructions for operating the apparatus and for controlling compounders that prepare a prescription admixture, with the memory including data relating to a plurality of the pharmaceutical components that may be transferred to prepare the prescription admixture, and data concerning the operating characteristics of the compounders that the apparatus is adapted to control. The apparatus determines the order of admixing by general rules of admixing and by categorized compatibility groups of components, so that the number of rinses that must be done are minimized (see at least Abstract) as taught by Kircher et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the system of Yuyama et al. in this way since all the claimed elements were known in the prior art and one skilled in the art

could have combined the elements as claimed by known systems/methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

CLAIM 14.

Claim 14 is directed to a system, wherein when a stored combination of medicine information has combination modification due to difference in combination order, the storage member stores the change, and when the pertinent combination is referred, medicine information is rearranged in an appropriate combination order and displayed on the display member. Claim 14 recites the same or similar limitations as those addressed above for claims 13. Claim 14 is therefore rejected for the same reasons as set forth above for Claim 13 respectively.

Claims 2, 9, 10 and 15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Yuyama et al. (US 7,333,938) in view of Walker et al. (US 7,366,675)

CLAIM 2.

Yuyama et al. teach(s) a medicine management system, comprising:

- a storage member for storing medicine information on medicines (see at least Figure 1; Col 1 || 49-56) and combination modification information showing change when a plurality of medicines are combined (see at least Col 9 || 43-63); and

- a combination adequacy judging member for judging combination adequacy based on the combination modification information stored in the storage member when two or more medicines are included in prescription information, (see at least Col 2 || 21-34) wherein
- the storage member stores medicine related information on respective medicines (see at least Col 3 || 61-64),

Yuyama et al. does not explicitly teach a system that calculate combinations of two or more medicines by a hash function based on the medicine related information to obtain at least one hash value, and stores combination modification information to relate the combination modification information with the at least one hash value obtained, and when the prescription information includes three or more medicines, the combination adequacy judging member calculates hash values based on the medicine related information stored in the storage member and searches whether or not a hash value of the hash values calculated by the combination adequacy judging member corresponds to one of the at least one hash value stored in the storage member, and when the hash value of the hash values calculated by the combination adequacy judging member corresponds to the one of the at least one hash value stored in the storage member, calls corresponding combination modification information from the storage member based on the obtained hash values to judge combination adequacy. It would have been obvious to one of ordinary skill in the art at the time of the invention to expand the system of Yuyama et al. to include data that may be encrypted using any known encryption algorithm (e.g., using a one-way hash function (see at least Figure 8, Col 26 || 10-45) as taught by Walker et al. One of ordinary skill in the art at the time of the invention would have been motivated to expand the

system of Yuyama et al. in this way since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known systems/methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

CLAIM 9.

Claim 9 is directed to a system for a member that stores a master file in which unrewritable combination modification information is stored and a case card file in which combination modification information can be newly stored, and during judgment of combination adequacy, the combination adequacy judging member judges combination adequacy preferentially based on the combination modification information stored in the case card file. Claim 9 recites the same or similar limitations as those addressed above for claims 3. Claim 9 is therefore rejected for the same reasons as set forth above for Claim 3 respectively.

CLAIM 10.

Claim 10 is directed to a system for a member for displaying the combination adequacy judged in the combination adequacy judging member, wherein combination modification information on combinations of all medicines displayed in the display member can be displayed. Claim 10 recites the same or similar limitations as those addressed above for claims 4. Claim 10 is therefore rejected for the same reasons as set forth above for Claim 4 respectively.

CLAIM 15.

Claim 15 is directed to a , wherein when the prescription information includes two or more medicines, the combination adequacy judging member selects medicines to be simultaneously administered based on procedure codes stored in the storage member before rearranging the medicine information according to the medicine codes. Claim 15 recites the same or similar limitations as those addressed above for claims 8. Claim 15 is therefore rejected for the same reasons as set forth above for Claim 8 respectively.

Response to Arguments

Applicant's arguments filed June 4, 2010 have been fully considered but they are not persuasive. In the remarks applicant argues (1) Yuyama fails to disclose a combination judging member that rearranges the medicine information according to medicine codes stored in the storage member when three or more medicines are included in the prescription information.

In response to argument (1), Examiner respectfully disagrees. As stated by Yuyama, it is Preferred, the combination related data file of the memory stores pH-values data for each injection, wherein the controller decides a mixing order of the injections contained in the injection prescription data in accordance with the pH-values data, and wherein the controller

displays the mixing order on the display. Thus, the mixing order of the injections can be automatically decided, thereby further enhancing the efficiency of the mixing work of injections.

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDWARD WINSTON whose telephone number is (571) 270-7780. The examiner can normally be reached on MONDAY-THURDAY; 9:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/E. W./
Examiner, Art Unit 3686
26 August 2010

/Gerald J. O'Connor/
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